State of California

Unified California Environmental Protection Agency

Policy and Guiding Principles

For External Scientific Peer Review

March 13, 1998

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I. INTRODUCTION

A. Goals

The California Environmental Protection Agency (Cal/EPA) views scientific peer review as the appropriate mechanism for ensuring that regulatory decisions and initiatives are based on sound science. Scientific peer review helps strengthen regulatory activities, establishes credibility with stakeholders, and ensures that Cal/EPA manages public resources effectively to meet its mission of protecting public health and the environment. In fact, when creating the Cal/EPA, Governor Wilson noted that regulatory decisions "must be based on rigorous and internally consistent science, at the level widely recognized to be the best available" (Governor's "Reorganization Plan Number One," April 16, 1991).

This document discusses the Cal/EPA's policy and guiding principles regarding how the various Boards, Departments, and Offices (BDO)[1] incorporate external scientific peer review into their regulatory decisions and related initiatives. The policy and guiding principles cover both the legislative mandate (Chapter 295, Statutes of 1997, Sher, thereafter referred to as Sher 1320) for external peer review of the scientific portion of rules establishing a regulatory level, standard or other requirement for the protection of public health in the environment, as well as Cal/EPA's directive calling for external peer review of the scientific basis of program initiatives. It provides for more consistency and uniformity across the various BDOs in terms of scientific peer review.

The Cal/EPA Peer Review Working Group (PRWG) developed and reviewed this document; the Working Group includes members from all of the Cal/EPA BDOs.

B. Background

The Cal/EPA and its constituent BDOs have numerous responsibilities for identifying and managing risks to public health and the environment. Over the last several years, the Cal/EPA BDOs have developed a number of different processes to carry out these responsibilities. Through these processes, scientists and other experts have been involved in developing and reviewing the information and data underlying the regulatory decisions of the BDOs.

In directing these efforts, Cal/EPA has worked to integrate and organize the peer review processes, to establish a hierarchy of levels for peer review, and to create a process for regularly evaluating the effectiveness of a BDOs peer review and involvement program. These efforts have and will continue to enhance the credibility of Cal/EPA's regulatory programs and other public initiatives.

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[1] The Cal/EPA BDOs include the Air Resources Board, Department of Pesticide Regulation, Department of Toxic Substances Control, Integrated Waste Management Board, Office of Environmental Health Hazard Assessment, and State Water Resources Control Board.

Specifically, the following state and federal work groups or committees have identified peer review as an important aspect of agency decision-making:

Risk Assessment Advisory Committee (RAAC),
Commission on Risk Assessment and Risk Management (Commission), and
U.S. Environmental Protection Agency (US EPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS)

In a recent report to Cal/EPA, the RAAC highlighted the importance of external peer review of regulatory activities as an important function that lends credibility to risk assessment while providing a mechanism for external input to the process.[2] The Committee recommended that:

> Cal/EPA should develop a formalized policy for internal and external peer review of its activities. It should identify goals and objectives of the program and Cal/EPA should design a program to meet its objectives.[3]

Further, the Governor's Executive Order W-137-96 requires Cal/EPA and its constitute BDOs to draft plans to implement recommendations of the RAAC.

Recently, with the passage of Sher 1320, the Cal/EPA was given impetus to integrate, organize, and augment its ongoing scientific peer review programs. Sher 1320 requires that no Cal/EPA BDO:

> ... shall take any action to adopt the final version of a rule ... [without submitting] ... the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer entity for its evaluation.

In addition to these state level calls for a specific guidance by Cal/EPA on peer review, recent activity on the national level has also focused on the importance of peer review in the regulatory process. The Commission noted that independent peer review plays a critical role in formulating scientific initiatives. As such, peer review is an important and effective mechanism for evaluating the accuracy or validity of technical data, observations, and interpretations, and scientific aspects of regulatory decisions and initiatives. The Commission further emphasized two important elements for effective peer review.

Peer review should provide balanced, independent views. When used well,

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2 California Environmental Protection Agency. *A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines*, October 1996. Chapter 2. Section E.1,p. 2-24. Sacramento, California.

3 Ibid

> peer review can serve as a system of checks and balances for the technical aspects of the regulatory process.
>
> Peer review should be conducted not simply to seek legitimacy for Agency decisions and positions, but to improve their quality.[4]

The US EPA OPPTS in its document entitled Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents underscored the need for peer review as follows:

> The purpose [and benefit] of peer review is to uncover any technical problems or unresolved issues for use in revising a preliminary product so that the final work product will reflect sound technical information and analyses. It should be noted that peer review is a process for enhancing the scientific or technical work product.[5]

In consideration of these state and national recommendations, Cal/EPA and its constituent BDOs are committed to creating a system for peer review. Specifically, this document provides general principles and specific direction regarding the creation of formal external scientific peer review by the Cal/EPA BDOs to comply with Sher 1320.

II. DEFINING CONCEPTS ASSOCIATED WITH SCIENTIFIC PEER REVIEW

This section defines a number of concepts related to scientific peer review. This discussion will help Cal/EPA BDOs comply with Sher 1320, meet RAAC recommendations for peer review, and establish other types of peer involvement.

A. External Scientific Peer Review

As required by Sher 1320, external scientific peer review means review by an independent scientific expert of the work product or products (or portions thereof) that constitute the scientific basis for a rule "... establishing a regulatory level, standard, or other requirement for the protection of public health or the environment." Sher 1320 defines "scientific basis" as "the foundations of a rule that are premised upon, or derived from empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment." Under Sher 1320, "rule" includes any regulation as defined in section 11342 of the Government Code and any policy adopted by the State Water Resources Control Board under the Porter-Cologne Water Quality Control Act (Division 7, commencing with section 13000 of the Water Code) that has the effect of a regulation.

To meet these requirements, the Secretary of Cal/EPA will be responsible for all peer review

4 *Risk Assessment and Risk Management in Regulatory Decision-Making* (1996), Section 5.5, p. 82.

5 Office of Prevention, Pesticide and Toxic Substances (OPPTS). *Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents*. October 1995. page 1.

activities. As such, the Secretary's Office will authorize the Cal/EPA PRWG as the panel for reviewing and approving any proposed peer review panel that performs multi-media or cross-media reviews (see pages 2 and 17, B1), as well as consolidating information on all reviews.

Peer review is an objective, critical review of a draft Agency scientific work product, typically by independent scientific experts. Although peer review can occur at several discrete points during the peer involvement process, it is typically characterized by a one-time interaction or a limited number of interactions by the peer reviewer(s). In these instances, peer review is part of the culmination of the work product development, ensuring that the final product is scientifically sound. Peer review can also occur during the early stages of a project or methods selection.

B. Peer Review in its Broader Function

Peer involvement can include expert participation in the development or review of the scientific portions of a work product supporting Agency initiatives. The purpose of this expert participation generally is to uncover any technical problems or unresolved scientific issues in a scientific work product so that the final work product will reflect sound scientific information and analyses. It should be noted that all peer involvement processes are intended to enhance the scientific work product.

As a part of peer involvement, peer input requires an open exchange of data, insights, and ideas between the agency staff responsible for developing of a work product and the experts consulted. Peer input is characterized by a continued and iterative interaction with the expert(s) during the early stages of peer involvement.

The subject matter experts who participate in a peer review process can be expected to undertake one of three related but different roles. First, they may work as paid or unpaid consultants with a significant role as author or advisor in developing a work product. Second, Cal/EPA BDOs may ask independent experts to provide peer input by participating in early developmental reviews or discussions of unfinished work products. Third, experts may be asked to serve as peer reviewers, providing critical evaluation and comments on work products nearing completion. This third role will commonly be used for Cal/EPA s external peer review process.

1. Formal vs Informal Peer Review

While other types of peer involvement may be carried out without formalized procedures, Cal/EPA BDOs should develop and implement official, written guidelines relating to external scientific peer review. This formality helps ensure the transparency of agency regulatory actions and enhance the credibility of agency decisions. Guidelines for external scientific peer review should address the basic aspects of the process such as which agency initiatives, risk assessments, regulatory options, or decisions will be subject to peer review. The Guidelines should discuss how the BDO will determine the level of peer review for a work product or initiative. The administrative features, such as how peer reviewers are selected and how to consider the outcomes of peer reviews, should

be discussed.[6]

2. Peer Review vs. Public Comment

External scientific peer review and public comment are not synonymous. Public comment is open to all issues, whereas the peer review process considers only the scientific issues. Public commentators usually include a broad array of people with an interest in the technical analysis or the regulatory decision; some are scientific experts, some are experts in other areas, and some are interested non-experts. The critical distinction is that public comment does not necessarily draw the kind of independent, expert information and analyses expected from the peer review process. Cal/EPA expects that, in general, external peer review occurs prior to release of a work product for public comment.[7]

C. Defining an Expert

In the context of peer review, an expert is someone who has demonstrated expertise in the subject matter required for the input or review function. For many agency decisions, a multi-disciplinary group of experts is often necessary for a full and complete peer review. The group will include an expert who corresponds to all the disciplines in the work project or initiative. For example, a risk assessment that relies on both animal and human data may often require experts in both areas for a complete review.

An independent expert is one who has not been associated with the generation of the specific work product either directly by substantial contribution to its development or indirectly by consultation during the development of the specific product. To be independent, an expert should be free from bias of any kind as to the issues under review. Such independence is necessary for objective, fair, and responsible evaluation of the work product under review.

For reviews required by Sher 1320, no person may serve as an external scientific peer reviewer for the scientific portion or basis of a rule if he or she participated in the development of the rule. The peer reviewer may not be employed by Cal/EPA or its BDOs except in the capacity as an independent external peer reviewer. For purposes of this prohibition, a member of one of Cal/EPA's or a BDO's scientific advisory panel is not an employee of the agency.

III. PLANNING FOR EXTERNAL SCIENTIFIC PEER REVIEW

This section discusses the elements that BDOs will need to consider when planning a work project or initiative for external scientific peer review. Specifically, the section discusses the types of

6 Policy Statement on Peer Review and Peer Involvement At The U.S. Environmental Protection Agency, June 7, 1994.

7 As required by state law, the Office of Environmental Health Hazard Assessment (OEHHA) currently does, and will continue to, allow public comment on certain work products prior to external peer review by the Air Resources Board's Scientific Review Panel (SRP), or OEHHA's Science Advisory Board (SAB), or as deemed appropriate to meet BDO management needs.

work projects or initiatives that do and do not require external scientific peer review, along with the necessary level of review.

A. Work Projects Requiring External Scientific Peer Review

Sher 1320 requires Cal/EPA BDOs to conduct an external scientific peer review of the scientific basis for any rule, as defined, establishing a regulatory level, standard, or other requirement for the protection of public health or the environment.

In addition, BDOs should also consider whether the scientific basis for a specific rule, major scientific initiative, or method not subject to the mandate of Sher 1320 should nevertheless be submitted for external scientific peer review.
Work products subject to review include:

1. Products that Address Emerging or Controversial Issues, Have Significant Cross-Media Implications, or Establish a Significant Precedent

Examples include the following:

a. Application of new scientific findings in hazardous waste classification.

b. Risk assessment methods, development, and findings, e.g., impacts concerning children or new environmental chemical fate transport models that substantially modify risk outcomes.

c. A work product that supports major regulatory decisions or initiatives of major impact.

2. Scientific Products that Support Regulations, Standards, or Rules

Examples include the following:

a. Risk assessments that form the basis for proposed rules (including associated hazard, dose-response, and exposure analyses).

b. Scientific studies, data, experiments, and modeling results that form the basis for proposed rules.

c. Critical technical guidance documents for the regulated community.

3. New Decision Criteria, Analytical Tools, or Models of Significance, or Changes in Assessment Methodologies to be Used Routinely in Risk Assessment

Examples include the following:

a. Newly developed or revised expert systems and quantitative techniques designed to help predict hazards, chemical fate, etc., from chemical structure, use, or toxicity/exposure data.

b. Significant new or revised models and other techniques designed to predict exposure, simulate transport, etc.

c. Changes or innovations in analytical measurement techniques for pollutants.

d. Decision criteria to be developed for the scientific aspects of classes of chemicals.

B. Work Projects Not Requiring External Scientific Peer Review

There are several circumstances when peer review work products do not require under SB1320. These work products include but are not limited to the following:

1. A particular work product that has been peer reviewed with a known record by a recognized expert or expert body. Additional review is not required if a new application of an adequately peer reviewed work product does not depart significantly from its scientific approach. These types of work projects would include standards developed by the U.S. EPA, which Cal/EPA adopts. This would include standards that Cal/EPA adopts from those developed by US EPA. These US EPA standards are presumed to have been sufficiently peer reviewed unless additional peer review is required by law.

2. Technical performance related to new control standards or manufacturing technologies, such as emission standards for new motor vehicles or consumer products. It is not the intent of Health & Safety Code section 57004 to review engineering data to support the technological feasibility of these standards or technologies.

3. Exploratory Analyses and Voluntary Risk Reduction. Cal/EPA is involved with a number of activities that involve exploratory scientific and technical analyses. For example, BDOs may collaborate with stakeholders and members of the regulated community to characterize the hazards, uses, exposure, and risks of a substance to identify pollution prevention opportunities. In other cases, alternative chemicals or processes may be used to set priorities for additional testing or information gathering. These scientific work products would not usually require peer review until such time that they would provide the basis for regulatory initiatives.

4. Administrative standards and rules which are primarily management directives for which the underlying scientific principles, computer models, or decision tools have already been appropriately reviewed.

5. The requirement for external scientific peer review under Sher 1320 does not apply to the adoption of emergency regulations under Government Code section 11346.1(b). However, in situations where a final regulation is to be adopted to replace the emergency regulation, Sher 1320 would apply to the final regulation, under the requirements set forth in this document.

6. Permit, variance standards, and conditions set by Cal/EPA BDOs, unless they are applied through regulation (e.g., permit by rule).

Appendix A is a list of Cal/EPA work products that may require external scientific peer review under Sher 1320 and this policy. This list is not necessarily inclusive of all work products that will go through external peer review, nor will all the work products on this list always require external peer review.

C. Level of Peer Review

The level of peer review should be commensurate with the level of scientific importance and regulatory impact of the decision to be made. Each BDO has the discretion and responsibility to choose the appropriate level of peer review. Generally, the more novel or complex the science, the greater the cost implications of the impending decision, the greater the potential for multi-media impact, or the more controversial the issue, the greater the need for an extensive and involved external peer review. Other work products may not need a large scale external peer review.

In determining the appropriate level of scientific peer review, the BDOs should consider the level of importance as part of their overall management needs as to whether the work project or initiative needs an extensive, moderate, or limited peer review. (See Appendix B, Matrix for Appropriate Level of Review.) The level of review must be determined at the time the work is planned so that peer review costs and time can be budgeted into the work plan.

1. Extensive Review

This level of review is a cornerstone of good management practice for any major initiative that has substantive scientific underpinnings. For an extensive review, the peer review group would ordinarily be a national body of experts selected in cooperation with the University of California (UC) President's Office. An extensive review is particularly needed in emerging areas of multi-media environmental protection. Initiatives that substantively cut across BDO organizational lines should have a firm scientific basis supported by extensive, external peer review. Primary examples include:

a. A work product supporting scientific initiatives of major impact.

b. A work product that has significant cross-agency, cross-media implication.

c. A work product that addresses controversial or significant emerging issues or establishes a significant precedent.

2. Moderate Review

This level of review typically would be used for a rule, establishing a regulatory limit, standard, or other requirement for the protection of public health or the environment that is based on substantive scientific information, where an extensive review is not warranted. In this case, an appropriate peer review group may include experts from the University of California, California State University, similar institutions, or be a collection of experts selected in cooperation with the UC President's Office. The primary examples include:

a. Work products that provide the scientific basis for a proposed rule as defined by Sher 1320.

b. A work product that satisfies a statutory or other legal mandate for peer review.

3. Limited Review

This level of peer review is for changes in analytical measurement methods or modifications in computer models. The appropriate peer reviewer(s) in this instance should be experts selected through appropriate mechanics by the Cal/EPA manager in charge of this activity. The external evaluation of these changes or modifications will provide support for agency actions based on data obtained by new measurement or modeling methods.

For example, results from peer-reviewed models used for evaluating site specific remediation will better survive legal scrutiny if challenged in court. For these reasons, it may be prudent to have the changes evaluated by external peers. At this level, obtaining the opinion of one or two experts should be sufficient. Examples of work products that should be considered for this level of review:

a. A work product that considers an innovative approach for a previously defined problem/process/methodology.

b. A work product that addresses a change in model development or analytical instrumentation.

c. A work product that establishes scientific decision criteria to be used in the regulation of a pesticide.

D. Formulate the Charge to the External Peer Reviewer

As part of the external scientific peer review process, Cal/EPA BDOs should formulate a clear, focused charge that identifies relevant issues and questions, invites comments or assistance, and presents specific issues that the BDOs expect the reviewers to address. This request signals a BDO's awareness of critical scientific issues and its receptivity to expert recommendations. The charge to peer reviewers should focus the review by specific questions, which also greatly simplify the task of collating, analyzing, and synthesizing peer review comments on a topical basis. Written

responses to these questions by peer reviewers help the agency create a peer review record.

The charge should identify the scientific portion of the rule and the scientific basis for the rule. This may be all or portions of the rule itself or the documents/work products to be presented in support of the rule. In reviewing all appropriate scientific aspects of the work product, the peer reviewers may also identify other important issues.

IV. CONDUCTING EXTERNAL SCIENTIFIC PEER REVIEW

This section discusses the principles used in conducting an external scientific peer review, including selecting peer reviewers. (See Appendix C, External Peer Review Process.)

A. Selecting Peer Reviewers

The success and usefulness of any external scientific peer review depends on the quality of the peer review draft, the care given to the statement of the issues or "charge," the match between the peer review draft and the form of peer review, the match between the peer review draft and the scientific/technical expertise of the reviewers, and use of peer review comments in the final product by the Cal/EPA. The Cal/EPA recognizes that to conduct external scientific peer review each of the foregoing elements requires serious attention.

An external scientific peer review panel or group, with an appropriate disciplinary mix, will often be required to provide a complete peer review of a complex work product. The make-up of such a group will depend on the time and resources available and the expertise required to treat the full range of issues/questions. Naturally, experts whose understanding of the specific scientific area(s) being evaluated are critical; nevertheless, it is also important to include other experts to completely evaluate all relevant scientific aspects of the work product. It may also be appropriate in some instances to have only a single external peer reviewer.

Ideally, peer reviewers should be free of real or perceived conflicts-of-interest or there should be a balancing of interests among peer reviewers. When reviewers are selected who may be perceived to have specific technical perspectives, such perspectives or potential conflicts of interest, real or perceived, must be identified and balanced to ensure credible peer review. As noted in Section II. C, an expert who provides peer input as an author, advisor, or early participant in the developmental reviews or discussion cannot be considered independent and unbiased for the given work product and should be excluded from most peer review activities. Such exclusion is required under Sher 1320.

1. Sources for Peer Reviewers

Potential peer reviewers can be identified and recommended from a number of organizations. Cal/EPA is developing a Memorandum Of Understanding and developed a Memorandum Of Agreement with the UC President's Office for the purpose of implementing the provisions of Sher 1320 and these Guidelines. The intent of the agreement with the UC President's Office is to create a mechanism for obtaining peer review expertise utilizing a rapid response task order process with the University of California system. Similar memoranda may be developed with other institutions of higher learning, including the California State University System. Specifically, Sher 1320 authorizes the following:

a. Enter into agreements between individual Cal/EPA BDOs and individual institutions with appropriate peer reviewers. In the case of the panel having several peer reviewers, the BDO may designate one of the reviewers as the chairperson or principal investigator for the panel;

b. Enter into an agreement with a peer review panel of highly qualified individuals with a variety of institutional affiliations. In such cases, the reviewer(s) must be approved by the Office of the President of the UC;

c. Enter into an agreement with the National Academy of Science; and

d. In some cases the make-up of the peer review entity is specified by statute. For example, the Health and Safety Code section 39661 provides that the Scientific Review Panel (SRP) established under Health and Safety Code section 39670 et seq. shall review the report prepared to assess the risk from and exposure to compounds that may be toxic air contaminants.

2. Constraints in Selecting Peer Reviewers

a. Where the external peer review entity is a multi-member panel, committee, or similar group, such as the SRP established under Health and Safety Code section 39670 et seq., legal counsel should be consulted to determine whether the Open Meeting Act, Government Code section 11120 et seq., applies to the actions of the panel, committee, or similar group.

b. Care must be taken to minimize the possibility for real or apparent conflicts of interest between the reviewers and the work product under review.

c. To evaluate Cal/EPA generated studies properly, some peer reviewers may need access to confidential business information (CBI). Whenever contemplating the use of outside peer reviewers, BDO staff should determine whether the reviewers will need access to CBI. If so, the Chief Counsel of the affected BDO should be consulted on whether it is practical to obtain the consent of CBI submitters to disclose the information to peer reviewers, as well as what steps must be taken to protect CBI in such situations.

3. Agency Review

The Secretary of Cal/EPA is ultimately responsible for all peer review activities. While many work products are media-specific and reasonably straightforward, in some cases the technical aspects of the review will cut across organizational lines, be multi-media in content, or be highly controversial. In these instances, the proposed peer review panel selections will be reviewed and approved by the Cal/EPA PRWG. The PRWG will have monthly meetings to review all peer review activities. These activities will be incorporated into a management tracking system maintained by the Secretary's Office. The PRWG is described in V.B.

B. Scheduling Peer Reviews

The peer review schedule is a critical feature of the process. The schedule must take into account the availability of a peer review quality draft work product, availability of appropriate experts, time available for using peer review comments, deadlines for the final work product, and logistical aspects of the peer review (e.g., contracting procedures).

The schedule for peer review should take into account the overall rulemaking (or other decision-making) schedule. Peer review sometimes leads to new information and analyses, or recommendations for new research that would alter the work product and thus modify the scientific/technical basis for the action. For this reason, the peer review process should usually be initiated as early as possible in the development of a proposed rule.

C. Materials to be Provided to Peer Reviewers

The materials to be reviewed by the external scientific peer reviewer(s) is the work product. For purposes of Sher 1320, a work product is a document or other instrument constituting the empirical data or other scientific finding, conclusion or assumption constituting the foundation of a rule as defined establishing a regulatory level, standard or other requirement for the protection of public health or the environment. Peer reviewers should receive these materials on a timely basis to conduct a complete review of the work product.

The individual BDOs are responsible for identifying the work product that provides the scientific basis for a proposed rule, as defined, as well as the level of review which is to be consistent with the policies and guiding principles set forth in this document. As noted in Section III above, peer review should be considered for the full field of possible work products that could benefit from peer review, and the full spectrum of peer review mechanisms for each product should be considered in making this determination.

Essential documentation for each peer reviewer includes:

a. The scientific portion of the proposed rule as defined.

b. Copies of the supporting scientific materials to be peer reviewed with associated background material and supporting documents. These materials comprise the findings, conclusions and assumptions upon which the rule in based.

c. A clear charge or statement of work seeking informed comment on identified issues to properly focus the efforts of the peer reviewers and ensure that their individual efforts can be merged.

d. A schedule for review including the date by which the reviewer must submit written comments or recommendations to the BDO.

e. The format for reviewer comments. Comments must be written and submitted in a format that facilitates the BDOs and public use.

f. BDO contact person.

g. Cal/EPA BDOs shall clearly state the appropriate responsibilities of the external scientific peer reviewer(s). This includes the reviewer's duty to ensure confidentiality of the peer reviewed work product. If the peer reviewer(s) will be informed of the need for confidentiality with regard to the release of Cal/EPA products that are stamped as "DRAFT" or "DRAFT - Do Not Cite, Quote, or Release." Premature release of draft BDO products, views, or positions is inappropriate and can be damaging to the credibility of the BDO or the peer reviewer. This action may also misinform the public in cases where data released prematurely do not stand up to peer review scrutiny. Other mechanisms to prevent the premature release of draft documents include a disclaimer that appears in a separate section at the front of the document and creating the document with watermarks clearly delineating DRAFT status (or a header or footer that states DRAFT status) on every page. In addition, in any solicitation for peer reviewers, the necessity for confidentiality and the non-release of materials, if appropriate, shall be emphasized.

Additional, useful materials that may be provided to peer reviewers include:

a. Information concerning the process the BDO is using for the peer review.

b. The name, address, and phone, fax, and/or Internet numbers of each peer reviewer working on the specific review.

c. Any scientific articles not covered in 1.h. from the literature that the BDO scientists deem relevant.

Peer reviewers should be given what is needed to complete their task: they should not be overburdened with excess material.

D. Evaluating Comments and Recommendations

Sher 1320 requires that:

> The board, department, or office may accept the findings of the external peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the board, department, or office disagrees with any aspect of the findings of the external scientific peer review entity, it shall explain, and include as a part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.

As noted in Section V. below, the Peer Review Coordinator should develop documentation that clearly demonstrates acceptance of the reviewers recommendations or delineates specific technical rationale for not accepting any or all of the review body's comments and recommendations.

E. Administrative Requirements

The Peer Review Coordinator must index and maintain the external scientific peer review record as a part of the official rulemaking record or, where no rulemaking record is required, maintain an archive. Such records are considered official records of the State of California and shall be subject to the relevant BDOs "records retention policy."

All peer review comments should be carefully evaluated and used to revise work products, where appropriate. In some cases, the BDOs may choose to prepare a document that responds to each comment. In other circumstances, comments may be addressed in a more general manner. In any case, a clear record must be maintained of the peer review process employed, as well as the specific comments received. Furthermore, the product itself must include some acknowledgment of the peer review process.

V. ACCOUNTABILITY AND RESPONSIBILITY IN THE CAL/EPA

This section provides information on the responsibilities of BDO line management for individual peer reviews and PRWG for general assistance and advice.

A. Line Management

1. Decision maker(s)

   a. The BDO Director/Executive Officer is accountable for the decisions regarding the identification of scientific work products and the mechanism(s) of peer review utilized for each of the products. The Director/Executive Officer is also responsible for ensuring that the peer reviews are performed as required.

   b. Specific responsibilities of the decision maker(s) including the following:

      i. Designating a Peer Review Coordinator to organize the peer review.

      ii. Providing advice, guidance, and support to the Peer Review Coordinator in the preparation, conduct, and completion of the peer review.

      iii. Establishing a realistic peer review schedule.

      iv. Designating the stage(s) of product development where peer review is appropriate.

      v. Ensuring that the results of peer review are adequately addressed in the final work product.

2. Peer Review Coordinator

   a. The Director/Executive Officer will designate a Peer Review Coordinator. The Peer Review Coordinator shall organize and oversee the peer review for a specific work product. The Peer Review Coordinator is authorized to prepare and bring to completion the peer review. The Peer Review Coordinator will obtain the assistance and support of others within the BDO to help support the peer review.

   b. Specific responsibilities of the Peer Review Coordinator include the following:

      i. Coordinate the peer review of the assigned work product.

      ii. Organize and facilitate the completion of the peer review following the

procedures outlined in this document.

iii. Select one or more peer reviewers as appropriate. This responsibility may require identifying a pool of candidates for the external scientific peer review effort in consultation with others involved with the peer review. The pool of candidates should then be submitted to the Office of the President of the UC as necessary. The coordinator shall take steps to identify and avoid any real or perceived conflicts-of-interest on the part of peer reviewers.

iv. Advise peer reviewers of their responsibilities.

v. Act as a liaison to the external scientific peer reviewer, or review team, group or panel. In this capacity, the coordinator shall facilitate the selection of a chairperson and provide staff support as required for the reviewer, chairperson and team, group, or panel.

vi. Report peer review activities to the Director/ Executive Officer of the affected BDO and the Cal/EPA Secretary.

vii. Collect and maintain the following materials for the external scientific peer review record, including at least:

--The draft work product submitted for peer review;

--Materials and information given to the peer reviewer(s);

--Comments, information, and materials received from the peer reviewer(s);

--Information about the peer reviewer(s) (e.g., names, affiliations, etc.);

--Any logistical information (e.g., times; locations; duration, etc.);

--The final work product.

B. California Environmental Protection Agency Peer Review Working Group

1. The PRWG will review and approve proposed peer review panels which perform multi-media or cross-agency reviews.

2. The PRWG will organize a quarterly review of the Cal/EPA's expected work products for the next fiscal year that will be subject to peer review. Where appropriate, this process should be integrated with the annual Rulemaking Calendar development process.

3. The PRWG will organize an annual review to assess the function of this policy in practice and to recommend changes

4. The PRWG will consist of one member from each BDO, as appointed by the BDO management. Each member will serve one year. The PRWG will be chaired by the Deputy Secretary for Science and Technology.

C. Legal Advice

The staff and management of Cal/EPA BDOs should continue to consult with their Offices of the Chief Counsel for legal advice or referral.

D. Budget

The Cal/EPA budget planning process for each fiscal year is the appropriate forum to ensure that peer review-related activities are appropriately budgeted and that sufficient resources will be available to effect a completed peer review.

The planning process articulates priority activities for the coming year and provides opportunities for periodic evaluation of project status, including opportunities for redirecting program priorities. The planning process facilitates development of project plans for priority projects, including identification of scientific products necessary to complete priority activities.

The project planning process provides a natural forum for discussing the nature of scientific products that will be developed to support various projects. This forum provides an opportunity to discuss the mechanism of peer involvement and/or peer review needed and how these peer activities will be achieved. Discussing the scope of peer review during the planing process provides the added benefit of ensuring that timing and resource requirements associated with peer review are included in the planning process and highlighted for senior management attention.

VI. REFERENCES

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Commission on Risk Assessment and Risk Management. 1996. *Risk Assessment and Risk Management in Regulatory Decision-Making.* Section 5.5.

US EPA Office of Prevention, Pesticides, and Toxic Substances. October 1995. *Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents.*

Appendix A

**CAL/EPA WORK PRODUCTS SUBJECT TO EXTERNAL PEER REVIEW UNDER SHER 1320*
(Chapter 245, Statutes of 1997, Sher)**

Board, Department, Office	Work Product	External Peer Review
Air Resources Control Board	Ambient Air Quality Standards (Stats. 1978, c. 429)	See Recommendations on Criteria Pollutants, below under OEHHA
	Exposure Assessment for Toxic Air Contaminants (H&SC Section 39650)	Science Review Panel (H&SC 39670)
Department of Pesticide Regulation	Risk Characterization Documents	US EPA
	Exposure Assessment Documents	US EPA
	Risk Assessments for Toxic Air Contaminants	Science Review Panel (H&SC 39670)
	Formal Departmental Reports that form the Scientific Basis for a Regulation	Independent Review
Department of Toxic Substances Control	Formal Departmental Reports that form the Scientific Basis for a Regulation	National Academy of Sciences
	Scientific Guidance Documents	Independent Review
Integrated Waste Management Board	Scientific Testing Documents	Independent Review
	Formal Board documents that form the basis of regulations containing prescriptive requirements	Independent Review

| Board, Department, Office | Work Product | External Peer Review |

Office of Environmental Health Hazard Assessment	Risk Assessments for Toxic Air Contaminants	Science Review Panel (H&SC 39670)
	Toxic Air Hot Spots Guidelines (SB 1731)	Science Review Panel (H&SC 39670)
	Hazard Identification Documents	Science Advisory Board
	Recommendations on Criteria Air Pollutants	Air Quality Advisory Committee
	Public Health Goals	Independent Review
	No Significant Risk Levels	Independent Review
	Maximum Allowable Daily Levels	Independent Review
	Chemical, Site or Process Specific Risk Assessments to be Used by Other Boards or Departments	Independent Review
	Chemical, Site or Process Specific Risk Assessments that are of Specific Concern to the Public	Independent Review
Regional Water Quality Control Boards	Regional Water Quality Control Plans, Policies, Guidelines, and Regulations or Amendments	Independent Review
State Water Resources Control Board	Statewide and Regional Water Quality Control Plans, Policies, Guidelines, and Regulations or Amendments	Independent Review

* This list was produced on the basis of a survey of rules and supporting work products currently used by the identified BDOs and is not necessarily inclusive of all work products that will be identified for external peer review nor will all the work products on this list always require external peer review.

Appendix B

CAL/EPA EXTERNAL SCIENTIFIC PEER REVIEW MATRIX FOR APPROPRIATE LEVEL OF REVIEW*

LEVEL	NATURE OF ISSUE	EXAMPLE PRODUCTS	TYPE OF PANEL
EXTENSIVE	-SIGNIFICANT CROSS-AGENCY IMPACTS -CONTROVERSIAL AND EMERGING ISSUES -SIGNIFICANT PRECEDENT	-NEW HAZARDOUS WASTE CLASSIFICATIONS -MULTI-MEDIA IMPACTS OF SIGNIFICANT MAGNITUDE -INITIATIVES IN WHICH SCIENTIFIC FINDINGS ARE AT ODDS WITH PUBLIC RISK PERCEPTION	-NATIONAL RESEARCH COUNCIL -MEMBERS FROM A NUMBER OF INSTITUTIONS SELECTED THROUGH UC PRESIDENT'S OFFICE -TECHNICALLY DIVERSE DUE TO NATURE OF ISSUES
MODERATE	-RULES THAT ESTABLISH A REGULATORY LEVEL, STANDARD, OR REQUIREMENT FOR THE PROTECTION OF PUBLIC HEALTH OR ENVIRONMENT	-IMPACTS ARE PRIMARILY SINGLE MEDIA -CONFLUENCE OF SCIENCE AND PUBLIC RISK PERCEPTION -RULES DEVELOPED BASED UPON SUBSTANTIVE BODY OF SCIENTISTS IN AGREEMENT WITH FINDINGS -NEW RISK ASSESSMENT MODELS/APPROACHES	-UC SYSTEM -CSU SYSTEM -SIMILAR INSTITUTION -MEMBERS FROM A NUMBER OF INSTITUTIONS SELECTED THROUGH UC PRESIDENT'S OFFICE -LESS NEED FOR EXTENSIVE TECHNICAL DIVERSITY
LIMITED	-NEW ANALYTICAL/ MEASUREMENT/ MODELING/ DECISION TOOLS	-DATA FOR RECOMMENDING NEW MEASUREMENT METHODS FOR CHEMICAL SPECIES -MODIFICATION OF APPROVED RISK ASSESSMENT MODELS -MODIFIED CRITERIA IN DECISION ANALYSIS TOOLS	-A SMALL GROUP OF TECHNICAL EXPERTS WHO CAN ADDRESS SPECIFIC ISSUE

* THIS MATRIX IS A GUIDE. THE ACTUAL LEVEL OF REVIEW AND TYPE OF PANEL WILL BE CHOSEN BASED ON AN ANALYSIS OF SPECIFIC FACTORS THAT REQUIRE PEER REVIEW.